JS

PATENT COOPERATION TREATY

14 JUL 2005

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATAENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	18 APR 2005

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
27359	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL04/00046	15 January 2004 (15.01.2004)	16 January 2003 (16.01.2003)

Applicant

GALIL MEDICAL, LTD.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide.*

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 27359	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/IL04/00046	International filing date *(day/month/year)* 15 January 2004 (15.01.2004)	Priority date *(day/month/year)* 16 January 2003 (16.01.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 5/02 and US Cl.: 600/486, 485, 585		
Applicant GALIL MEDICAL, LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 June 2004 (17.06.2004)	21 February 2005 (21.02.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Navin Natnithithadha Telephone No. (571) 272-2975

Form PCT/IPEA/409 (cover sheet)(January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL04/00046

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-16 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages 17-20 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the drawings:
pages 1-2 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages None
☒ the claims, Nos. None
☒ the drawings, sheets/figs None
☒ the sequence listing (*specify*): None
☒ any table(s) related to the sequence listing (*specify*): None

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL04/00046

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3, 7-23	YES
	Claims	1,2,4-6	NO
Inventive Step (IS)	Claims	13-23	YES
	Claims	1-12	NO
Industrial Applicability (IA)	Claims	1-23	YES
	Claims	NONE	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 13 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: the claim ends with two periods.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:
Claims 1, 2 and 4-6 lack novelty under PCT Article 33(2) as being anticipated by EINZIG '153.

In regards to claims 1 and 4, Einzig teaches a balloon catheter for detecting obstruction of blood flow within a blood vessel (see fig. 24 and col. 23, lines 25-35), comprising:

a. a controllably inflatable balloon 128 (see fig. 12 and col. 18, line61);
b. a first pressure sensor (optical fiber 118 terminating at sensitive zone 126 proximal of the balloon);
c. a second pressure sensor (optical fiber 116 terminating at sensitive zone 122 distal of the balloon).

The method of claim 4 contains the same subject matter as claim 1 and is therefore rejected for the reason above.

As to claim 2, Einzig teaches the first and second pressure sensors report pressure measurements to a data receiver 326 by fiber optic wire connections.

As to claim 5, Einzig teaches monitoring two pressures , an abrubt narrowing in the vessel of finite length (stenosis) 410 is detected by observing a difference in the two pressures (see col. 23, lines 31-35).

As to claim 6, Einzig teaches determining the presence and location of stensois by using pressure sensors (see col. 6, line 41-42).

Claim 3 lacks an inventive step under PCT Article 33(3) as being obvious over EINZIG '153 in view of RINDNER '588.

As to claim 3, Einzig does no teach wireless pressure sensors. However, it is well known in the art at the time the invention was made to transmit pressure signals wirelessly. For example, Rindner teaches both wired and wireless means for transmitting pressure signals from the distal end of a catheter (see col. 2, lines 17-20).

Claims 8-12 lack an inventive step under PCT Article 33(3) as being obvious over EINZIG '153 in view of VAN WORMER '837.

As to claims 8-12, Einzig does not disclose determining the position of the balloon by an imaging modality such as an ultrasound system and using a radio-opaque marker. However, this is well known in the art at the time the invention was made. Van Wormer teaches determining a position of a balloon 10 on a catheter by using ultrasonic scanning of radio opaque markers 23, 24 (see fig. 2, col. 3, lines 52-56, and col. 4, lines 17-19).

INTERNATIONAL PRELIMINARY [redacted]PORT ON PATENTABILITY

International a[redacted]tion No.
PCT/IL04/00046

Supplemental Box

Claim 7 lacks an inventive step under PCT Article 33(3) as being obvious over EINZIG '153 in view of LIN '233.

As to claim 7, Einzig does not teach determining the position of the balloon using a scale. However, it is well known in the art at the time the invention was made to measure the penetration of a catheter and hence the location of a balloon attached to the catheter using a scale. For example, Lin teaches a balloon catheter and using scale 46 for determining the length of penetration of the catheter 10 with a balloon 24 at the proximal end 14 (see col. 3, lines 47-50).

Claims 13-22 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for measuring an internal dimension of a blood vessel, comprising determining an external dimension of the balloon by measuring the pressure between the outer wall of the balloon and the inner wall of the blood vessel. Houser, US 5,865,801 A, teaches a balloon catheter having piezoelectric sensor film 82 for detecting contact of the outer wall 42 of a balloon with the inner wall of a blood vessel. These sensors are not used to determine the internal dimensions of the blood vessel.

Claim 23 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for distinguishing between standard plaque and vulnerable plaque in a blood vessel comprising: reporting presence of standard plaque and reporting the presence of vulnerable plaque based on the pressure reported between the outer wall of the balloon and the inner wall of the blood vessel.